Device & IDE Study Path

Pre-submission → PBC Review (if required) → Ancillary Committee(s) Review → MCRU Review (if required) → IRB Review

IRB Approval with contingency

Study Team provides documentation device is under CED policy and uploads into eRPM.

CRAO confirms documentation is appropriate at Leadership Review Meeting

Study Activity Begins → IRB completes review and issues approval → CRAO completes review and issues approval → Study team submits Amendment and uploads MAC part A/B approval letters

PI Submits → PI Re-Submits

Blue = eRRM Project Status
Green = PI Activities
Pink = CRAO/IRB (eRRM) Activities

Approved by: CRAO Director
Date: 11.15.2012

Revised: 11.15.2012

Calendar Review Analysis Office

Device Study Procedure Flow